RECEIVED
CENTRAL FAX CENTER

JUN 2 3 2010

In the Claims:

- 1. (Currently amended) A method of detecting the presence or absence of invasive trophoblast cells in a patient at risk for gestational trophoblastic disease or having a germ cell tumor comprising the steps of:
 - a. obtaining a urine, saliva, scrum or plasma sample from said patient;
 - b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG and ITA in the sample or comprises the total amount of intact hCG plus the amount of free β subunit of hCG and ITA in the sample;
 - c. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA;
 - d. determining the percentage of the amount of hCG determined in step b that is ITA, and
 - e. determining that invasive trophoblast cells are present in the patient if the percentage of the amount of HCG that is ITA determined in step d is 30% or greater such that a diagnosis of gestational trophoblastic disease or the existence of a germ cell tumor may be made, wherein the amount of hCG comprises the total amount of intact hCG and ITA plus the amount of free β sub unit of hCG in the sample.
- 2. (Canceled)
- 3. (Cancelled)
- 4. (Cancelled)
- 5. (Cancelled)
- 6. (Original) The method of claim 1, wherein the patient is a woman previously diagnosed as having a gestational trophoblastic disease.
- 7. (Original) The method of claim 6, wherein the gestational trophoblastic disease is hydatidiform mole.

Amendment/Response 6-10 N12-003USRCE.amendment 6-10.doc

2

10/616,323 Att'y Docket N12-003US

- 8. (Original) The method of claim 6, wherein the gestational trophoblastic disease is choriocarcinoma.
- 9. (Previously presented) The method of claim 6, wherein the gestational trophoblastic disease is placenta-site trophoblastic tumor.
- 10. (Previously presnted) The method of claim 1, wherein the biological sample is urine, plasma or serum.
- 11. (Original) The method of claim 10 wherein the biological sample is urine.
- 12. (Previously presented A method of diagnosing quiescent gestational trophoblastic disease in a patient previously diagnosed as having quiescent gestational trophoblastic disease or previously diagnosed as having a gestational trophoblastic disease comprising the steps of:
 - a. obtaining a urine, saliva, scrum or plasma sample from said patient, wherein said patient has persistently low hCG titers;
 - b. determining the amount of hCG in the sample wherein the amount of hCG comprises the total amount of intact hCG plus ITA in the sample or comprises the total amount of intact hCG plus ITA plus the amount of free β subunit of hCG in the sample;
 - c. determining the total amount of ITA in the sample in an immunoassay which determines the selective binding of monoclonal B152 to ITA;
 - d. determining the percentage of the amount of hCG from step b that is ITA, and
 - e. diagnosing quiescent gestational trophoblastic disease in said patient if the
 percentage of total hCG that is ITA determined in step (d) is less than
 30%.
- 13. (Previously presented) The method of claim 12, wherein the patient is a woman previously diagnosed as having a gestational trophoblastic disease.
- 14. (Previously presented) The method of claim 13, wherein the gestational trophoblastic disease is hydatidiform mole.
- 15. (Previously presented) The method of claim 13, wherein the gestational trophoblastic disease is choriocarcinoma.

- 16. (Previously presented) The method of claim 13, wherein the gestational trophoblastic disease is placenta-site trophoblastic disease.
- 17-45. Cancelled.
- 46. (Canceled)
- 47. (Previously presented) The method of claim 12, wherein the amount of hCG comprises intact hCG, ITA and the free \(\beta \) subunit of hCG.